

### REMARKS

**The rejection of claims 1 to 18 as being anticipated by Forman et al (US 6,692,458) is traversed.**

The rejection does not make out a *prima facie* case for anticipation because there is no claim element-by-element comparison with Forman et al. The single sentence in the Action regarding the basis for the rejection is insufficient to make out a case of anticipation.

Forman et al do not disclose several of the elements of the rejected claims including:

- constraining the heart with the increased fluid pressure in the pericardial sac. (independent claim 1)
- monitoring the fluid pressure in the pericardial sac (independent claim 15).  
Contrary to the Action, Forman et al do not teach monitoring a pressure of the pericardial sac.
  - comparing the fluid pressure in the sac to a target and draining some fluid if the target is exceeded (claim 13)
- increasing a fluid pressure in the pericardial sac by the infusion of fluid (independent claim 11 and dependent claim 16).
  - increasing fluid pressure by 5 to 10mmHg (claim 9).
  - supplying the fluid from an elevated source of fluid (claim 14)
- maintaining
- reducing dilation in the heart (claim 11).
- regulating the pressure of the infused fluid (claim 16).
  - regulating the pressure of the infused fluid with a pump controller (claim 17)

- regulating the pressure based on a pressure target (claim 18).

Forman et al disclose a catheter and a method delivery of medicament to or collecting agents from biological spaces, including the pericardium. There is no suggestion in Forman et al that sufficient fluid is to be infused into the pericardium to increase the fluid pressure therein, to constrain the heart or to monitor the pressure of the pericardium. Further, Forman et al do not suggest that a weakened heart may be treated by constraining the heart with fluid pressure added to the pericardium.

**The rejection of claims 1 to 3, 5 to 9 and 11 to 18 as being anticipated by Schmidt et al (US 6,206,004) is traversed.**

The rejection does not make out a *prima facie* case for anticipation because there is no claim element-by-element comparison with Schmidt et al. The single sentence in the Action regarding the basis for the rejection is insufficient to make out a case of anticipation.

Schmidt et al do not disclose several of the elements of the rejected claims including:

- constraining the heart with the increased fluid pressure in the pericardial sac. (independent claim 1),
- reducing dilation in the heart (claims 1 and 11).
- monitoring the fluid pressure in the pericardial sac (independent claim 15).  
Contrary to the Action, Schmidt et al do not teach monitoring a pressure of the pericardial sac.
  - monitoring the fluid pressure until it exceeds a predetermined fluid pressure (claim 1)

- comparing the fluid pressure in the sac to a target and draining some fluid if the target is exceeded (claim 13)
- increasing a fluid pressure in the pericardial sac by the infusion of fluid (independent claim 11 and dependent claim 16).
  - increasing fluid pressure by 5 to 10mmHg (claim 9).
  - supplying the fluid from an elevated source of fluid (claim 14)
- regulating the pressure of the infused fluid (claim 16).
  - regulating the pressure based on a pressure target (claim 18).

**New claims have been added.**

The new claims are supported in the specification at, for example, paragraph 0057 of US Pat. Appl. Pub. 2004/0193138 which describes a hydraulic infusion solution -- which is an example of a flowable material -- being infused into the pericardial sac to increase pressure in the sac by 5mmHg to 20mmHg; paragraph 0048 that describes a hydraulic shell formed by the infused flowable material that forms a heart restrictor; paragraph 0040 describes constraining the heart and reducing the diastolic dilation of the heart using the invention, and paragraph 0060 describes the algorithm of infusing a fluid in the pericardial sac to adjust the volume of fluid in the sac, and to increase the pressure in the sac between 5mmHg and 20mmHg.

The new claims are directed to constraining the heart and/or forming a hydraulic shell around the heart by infusing of a flowable material in the pericardial sac. These features are not disclosed in Schmidt et al and Forman et al.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: /Jeff Nelson/

Jeffrey H. Nelson  
Reg. No. 30,481

JHN:glf  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100